REMARKS/ARGUMENTS

Claims 1-26 are pending in the above-referenced matter. Claims 21-26 are newly added to further define the scope of the claim coverage. Support for the new claims may be found throughout the specification, figures and claims. Accordingly, no new matter has been added thereby.

Claims 1, 5, 6, 10, 11, 15, and 19 have been amended only to more clearly define Applicant's invention but NOT to distinguish over the cited art. With respect to claim 10, as further discussed below, the Villa reference does not and cannot operate with the two arms collapsed in front of the needle in "a ready to use position". As such, the amendment to claim 10 was not made to distinguish over Villa but to merely further clarify the scope of the claim.

This is a response to the Office Action dated September 26, 2008 wherein the Examiner rejected claims 1-20 under §102(e) in view of WO 03/011381 to Villa, the first name inventor.

In view of the remarks that follow, reconsideration and a notice of allowance are respectfully requested.

Claims 3, 5-8, 14-15, and 18-20 are objected to but would be allowable if amended in independent form to include all of the limitations of the base claim and any intervening claims. However, in view of the remarks that follow, Applicant respectfully declines to amend these claims at this time.

TELEPHONE INTERVIEW

A Telephone interview was conducted on Monday, December 15, 2008 between Examiner Anderson and Tom Dao, attorney of record. During the interview, claims 1 and 5 were discussed. The cited prior art, WO 03/011381 A1, was also discussed. It was agreed that the cited art does not show a valve located inside a catheter hub and therefore cannot anticipate claims 1 and 5 under §102(e).

§102(e) Rejection of Claims 1, 2, 4, 9-13, and 16-17

Claims 1, 2, 4, 9-13, and 16-17 are rejected under §102(e) by WO 03/011381 to Villa. In rejecting independent claim 1, the Examiner contends:

> *Villa discloses (figures 1-13) a catheter insertion device (4) comprising a hollow-cylindrical catheter hub (11) having a catheter tube (10) attached at a distal end thereof, a needle hub (6) having a hollow needle (5) attached thereto and extending through the catheter hub and the catheter tube when in a ready position, a needle guard element (19) arranged displaceably on the needle in the catheter hub, wherein a check valve (16) is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle.* (Emphasis added).

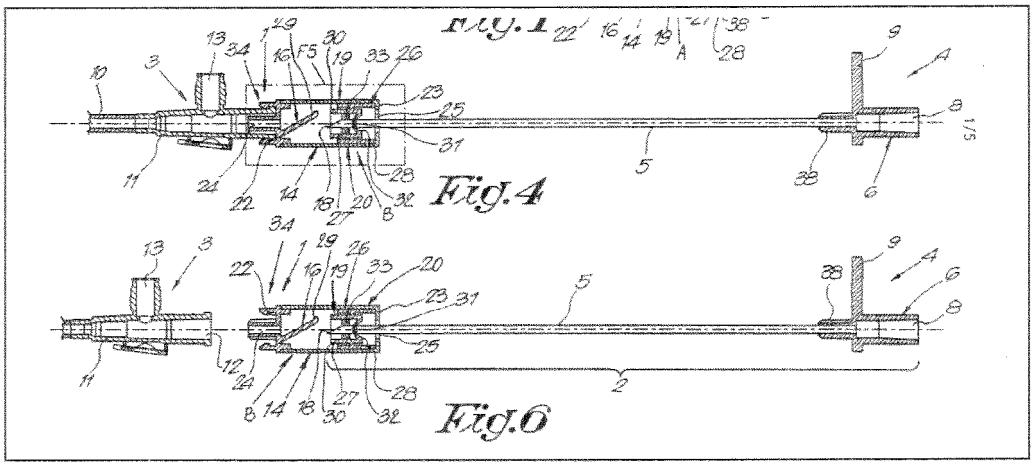
"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987, emphasis added).

Claim 1 recites, in part, a catheter insertion device comprising a hollow catheter hub having a catheter tube, a needle hub having a hollow needle extending through the catheter hub and the catheter tube when in a ready position, a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter hub, wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle.

Applicant respectfully disagrees with the rejection, among other things, because Villa does not disclose a "check valve [] disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position". Furthermore, the Examiner's recitation of claim 1 as a substitute of what Villa supposedly disclosed to reject claim 1 is not helpful and may appear to be in violation of 35 U.S.C. §132, which requires a well articulated and reasoned Office Action so that Applicant may be properly notified of the reasons for the rejection of the claim so that he or she can then decide how best to proceed. Merely restating claim 1 to reject claim 1 without referring to the Villa specification with specificity appears to run counter with the intentions of §132.

The Examiner points to element "16" of Villa as being "a check valve (16)" (OA, page 3). However, Villa discloses a cannula needle 2 comprising a protective means 14 which comprises a "safety means 16 having at least one part, in this case, a safety tongue 17, which upon retraction of the needle 5, is placed in front of the point 18 of the needle 5, such as to prevent the re-use of this needle. . ." (Villa, page 10 and FIGs. 4/5). Furthermore "[t]he safety tongue 17 consists of an elastically bendable lip, which in this case forms one part with the end wall 22, and which is configured and arranged in such a manner that, in its free position, it extends through the path of the needle 5, preferably in an oblique manner, as shown in figures 4 to 6." (Villa, page 11).

In short, Villa discloses a catheter assembly that comprises a needle hub and needle 4, a protective device 1 for shielding the tip of the needle, and a catheter hub 3 having a catheter tube. NOWHERE does Villa disclose a check valve. The protective device 1 is not a valve. Instead, it has a safety tongue 17 that functions to block the needle tip once the needle is pulled into the housing (FIG. 6). In this position, the safety tongue 17 springs upward to block the needle from moving back out the housing 20. Furthermore, even if the "safety means" is a valve, a position that Applicant adamantly opposes, the safety means 16 is NOT "disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position". In fact, only the passage opening 24 of the housing 20 projects into the catheter hub in a ready position (FIG. 1) and the safety means 16 is located outside of the catheter hub and separates from the catheter hub (FIG. 6). Thus, even if the safety means 16 is a valve, it does nothing to block the flow of blood coming through the catheter tube and spilling out the catheter hub once it detaches from the catheter hub.



Accordingly, as Villa failed to disclose a valve and failed to disclose a valve positioned in a catheter hub, as it separates from the catheter hub as shown in FIG. 6, Villa failed to anticipate claim 1 as required under §102(e) by disclosing each and every element of claim 1.

Because claims 2, 4, and 9 depend, either directly or indirectly, from claim 1, they too are allowable for at least the same reasons.

Although claim 2 is allowable because of claim 1, it is further independently allowable for at least the following reason. Claim 2 depends from claim 1 and further recites "wherein the

catheter hub comprises a distal hub element and a proximal hub element, and the check valve is held between the distal hub element and the proximal hub element, which are joined to one another".

In rejecting claim 2, the Examiner again merely recited the words of claim 2 without pointing to the spec or disclosure of the Villa reference. Indeed, if the Examiner were to point to Villa, the Examiner will realize that element 16 is part of the housing 20 of the protective means 14 (FIG. 6 and page 11) and is NOT part of or attached to the catheter hub 3. If it were, then it could not separate to block the needle tip, as shown in FIG. 6. Accordingly, as the rejection is faulty, the rejection should be rescinded.

In rejecting claim 4, the Examiner again merely recited the words of claim 4 without point to the spec or the disclosure of the Villa reference. If the Examiner were, the Examiner would realize that FIGs. 7-13 represent alternative embodiments that do not incorporate element 16 of FIGs. 1-6. As such, the combination FIGs. 1-6 and FIGs. 7-13 cannot include both element 16 and a guard having two arms 42 as shown in FIGs. 7, 10 and 12. Hence, the combination provided by the Examiner failed to disclose a "valve".

Claim 4 recites "[t]he device according to claim 1, wherein the catheter hub comprises an inner circumference and a radial projection projecting radially from the inner circumference, which is configured to engage with the needle guard element in the ready position." As shown in FIGs. 2, 3, 5, and 7-12 of the Villa reference, a detent engagement is used between the locking portions 36 and the collar 37 to engage the needle guard housing with the catheter hub. NOWHERE does Villa disclose a radial projection projecting radially from the inner circumference, which is configured to engage with the needle guard element in the ready position.

In rejecting independent claim 10, the Examiner again merely recited the words of claim 10 without pointing to the spec or the disclosure of the Villa reference. In particular, the Examiner contends that Villa discloses "a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and a needle guard element comprising two needle guard arms

(figures 1 and 8) crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve." (OA, page 4).

Independent claim 10 recites, in part, a catheter insertion device comprising a catheter tube attached to an end of a catheter hub; a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve.

Applicant respectfully disagrees with the rejection. Among other things, the Examiner merely points to FIGs. 1 and 8 of Villa as support. However, whereas FIG. 1 of Villa is directed to a protective means 14 comprising a single arm 16 (called "safety means"), which is made of a "safety tongue 17", FIG. 8 is directed to a different embodiment (See, e.g., page 9, first paragraph), which comprises two elastically bendable first portions 42 (page 15). Thus, the two figures relied on by the Examiner are not combinable or compatible. Furthermore, NOWHERE is disclosed a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub. The only feature disclosed and the only feature relied on by the Examiner is a safety feature, which is configured to block the needle tip to prevent needle stick. The same safety feature is NOT a valve for regulating fluid flow. As stated above, the safety feature separates from the catheter and therefore cannot regulate fluid flow since the catheter hub is left exposed.

Still furthermore, Villa does not disclose "a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve". Among other things, Villa discloses a safety device located in a separate housing 20 (See, e.g., FIG. 6). As such, the safety devices disclosed by Villa, especially the embodiments with two arms, FIGs. 7-13, are not positioned inside the catheter hub.

Yet still furthermore, as shown in FIG. 8, the only way the two distal ends 43 of the two flexible arms 42 cross the needle axis is in the protective position, where they come together to cover the needle tip. In the protective position, however, the two needle guard arms of the Villa device CANNOT be positioned in the catheter hub adjacent the valve as doing so would require

the assembly to be in a ready position, not a protective position. As such, the suggestion produces a nonsensical result.

Accordingly, as Villa failed to disclose each and every element of claim 10, Villa failed to anticipate claim 10 under §102(e).

Because claims 12 and 13 depend from claim 10, they too are allowable for at least the same reasons as claim 10.

Independent claim 11 recites, in part, a catheter insertion device comprising a catheter tube attached to an end of a catheter hub; a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube and comprising an engaging section near a needle tip; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub, said valve comprising an opening and the needle projecting through the opening; and a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub.

As discussed above, Villa does not disclose a valve for regulating fluid flow. Instead, Villa only discloses a safety means 16 for protecting or shielding the needle tip. Furthermore, the safety means 16 is located in a separate housing 20 (Figs. 1-5) and therefore cannot be located inside the catheter hub. Still furthermore, element 16 is a "safety tongue 17" and therefore does not include "an opening and the needle projecting through the opening" as recited by claim 11. Still furthermore, since Villa does not disclose a valve, it cannot disclose the limitation "a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub." Still furthermore, since the safety means separate from the catheter hub in the protective position to shield the needle tip, it cannot regulate blood flow through the catheter hub.

Accordingly, Applicant submits that Villa failed to anticipate claim 11 as required under §102(e).

Because claims 16 and 17 depend from claim 11, they too are allowable for at least the same reasons.

New claims 21-26 are dependent claims and depend from claim 1, 10, or 11. As such, claims 21-26 are patentable for at least the reasons discussed above for claim

In view of the remarks set forth above, the application is thought to be in condition for allowance and early notice thereof is respectfully solicited.

Should the Examiner find it necessary to speak with Applicant's attorney, he is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,

KLEIN, O'NEILL & SINGH, LLP

By _____

Tom H. Dao
Reg. No. 44,641
949/955-1920

THD/mxl